

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarterly Period Ended June 30, 1999

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 1-9898

**ORGANOGENESIS INC.**

(Exact name of registrant as specified in its charter)

<u>Delaware</u>	<u>04-2871690</u>
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification number)

<u>150 Dan Road, Canton, MA</u>	<u>02021</u>
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (781)575-0775

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes (X) No ( )

The number of shares outstanding of registrant's Common Stock, par value \$.01 per share, at August 2, 1999 was 30,485,630 shares (excluding treasury shares).

**ORGANOGENESIS INC.**Index

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**PART I - FINANCIAL INFORMATION**

## Item 1 - Financial Statements

**ORGANOGENESIS INC.**Consolidated Balance Sheets  
(In thousands, except share data)

	December 31, <u>1998</u>	June 30, 1999 <u>(unaudited)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$5,052	\$4,051
Investments	12,789	16,350
Inventory	730	780
Other current assets	<u>441</u>	<u>1,138</u>
	19,012	22,319
Property and equipment -		
Less accumulated depreciation of \$9,339 and \$10,208	7,605	10,526
Other assets	<u>93</u>	<u>646</u>
	<u>\$26,710</u>	<u>\$33,491</u>
Liabilities		
Current liabilities:		
Accounts payable	\$1,036	\$474
Accrued expenses	<u>2,435</u>	<u>2,733</u>
	3,471	3,207
Long-term debt	-	17,772
Commitments (see notes)		
Stockholders' Equity		
Preferred stock, par value \$1.00; authorized 1,000,000 shares:		
Series C convertible preferred; designated 200 shares;		
62 shares issued and outstanding as of December 31, 1998	-	-
and June 30, 1999, respectively		
Common stock, par value \$.01; authorized 80,000,000 shares:		
issued and outstanding 30,479,719 and 30,526,753 shares	305	305
as of December 31, 1998 and June 30, 1999, respectively		
Additional paid-in capital	124,342	127,340
Accumulated deficit	(101,017)	(114,533)
Treasury stock at cost, 40,000 and 60,000 shares as of		
December 31, 1998 and June 30, 1999, respectively	<u>(391)</u>	<u>(600)</u>
Total stockholders' equity	<u>23,239</u>	<u>12,512</u>
	<u>\$26,710</u>	<u>\$33,491</u>

The accompanying notes are an integral part of the consolidated financial statements.

**ORGANOGENESIS INC.**Consolidated Statements of Operations  
(Unaudited, in thousands, except share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	<u>1998</u>	<u>1999</u>	<u>1998</u>	<u>1999</u>
Revenues:				
Research and development support from related party	\$4,750	\$-	\$6,750	\$-
Product sales to related party, royalties and other income	308	624	502	1,111
Interest income	<u>321</u>	<u>314</u>	<u>393</u>	<u>507</u>
Total revenues	<u>5,379</u>	<u>938</u>	<u>7,645</u>	<u>1,618</u>
Costs and Expenses:				
Research, development and operations	3,873	5,568	7,786	10,661
General and administrative	1,191	1,654	2,411	3,168
Non-recurring, non-cash purchase of technology	-	900	-	900
Interest expense, net	-	<u>405</u>	-	<u>405</u>
Total costs and expenses	<u>5,064</u>	<u>8,527</u>	<u>10,197</u>	<u>15,134</u>
Net income (loss)	<u>\$315</u>	<u>\$(7,589)</u>	<u>\$(2,552)</u>	<u>\$(13,516)</u>
Net income (loss) per common share - basic and diluted	<u>\$ .01</u>	<u>\$( .25)</u>	<u>\$( .09)</u>	<u>\$( .44)</u>
Weighted average number of common shares outstanding - basic and diluted	<u>29,281,065</u>	<u>30,468,876</u>	<u>29,120,006</u>	<u>30,460,791</u>

The accompanying notes are an integral part of the consolidated financial  
statements.

**ORGANOGENESIS INC.**Consolidated Statements of Cash Flows  
(Unaudited, in thousands)

	For the Six Months Ended June 30,	
	<u>1998</u>	<u>1999</u>
Cash flows from operating activities:		
Net loss	\$(2,552)	\$(13,516)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	700	869
Amortization of warrants and deferred debt issuance costs relating to long-term debt	-	113
Issuance of treasury stock for purchase of technology	-	900
Changes in assets and liabilities:		
Other current assets	(709)	(747)
Accounts payable	288	(562)
Accrued expenses	201	298
Deferred rent payable	(21)	-
Cash used in operating activities	<u>(2,093)</u>	<u>(12,645)</u>
Cash flows from investing activities:		
Capital expenditures	(456)	(3,690)
Purchases of investments	(14,166)	(19,000)
Sales/maturities of investments	<u>6,536</u>	<u>15,439</u>
Cash used in investing activities	<u>(8,086)</u>	<u>(7,251)</u>
Cash flows from financing activities:		
Proceeds from issuance of long-term debt	-	20,000
Deferred debt issuance costs	-	(575)
Proceeds from sale of preferred stock, net	19,117	-
Proceeds from sale of common stock	6,000	-
Proceeds from exercise of stock options	915	218
Purchase of treasury stock	-	(748)
Cash provided by financing activities	<u>26,032</u>	<u>18,895</u>
Increase (decrease) in cash and cash equivalents	15,853	(1,001)
Cash and cash equivalents, beginning of period	<u>333</u>	<u>5,052</u>
Cash and cash equivalents, end of period	<u>\$16,186</u>	<u>\$4,051</u>

The accompanying notes are an integral part of the consolidated financial  
statements.

**ORGANOGENESIS INC.**Notes to Consolidated Financial Statements  
(Unaudited)1. Basis of Presentation:

The accompanying unaudited consolidated financial statements of Organogenesis Inc., have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of the financial position, results of operations and changes in cash flows for the periods presented. The results of operations for the six months ended June 30, 1999 are not necessarily indicative of the results to be expected for the year ending December 31, 1999.

These financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 1998 as filed with the Securities and Exchange Commission.

Certain reclassifications have been made to the prior period financial statements to conform to the current presentation.

2. Inventory:

Inventory is stated at the lower of cost or market, cost being determined using the first-in, first-out method of accounting. Inventory consisted of the following (in thousands):

	December 31, <u>1998</u>	June 30, 1999 <u>(unaudited)</u>
Raw Materials	\$300	\$316
Work in Process	<u>430</u>	<u>464</u>
	<u>\$730</u>	<u>\$780</u>

3. Other Current Assets:

Included in other current assets is a net receivable due from Novartis of approximately \$213,000 at December 31, 1998 and \$471,000 at June 30, 1999. Cash payments were collected subsequent to June 30, 1999.

4. Convertible Debt:

On March 31, 1999, we completed a financing of \$20,000,000 through the private placement of five-year convertible debentures and 400,000 warrants to purchase common stock. The debentures are convertible at a fixed price of \$14.50 per share at any time on or after March 30, 2000. Interest on the debentures accrues at 7% annually, payable in cash, common stock (at the average trading price for the twenty trading days preceding the due date) or any combination thereof, at our option, semi-annually on September 30 and March 31 or on the date any of the principal outstanding under the notes has been converted into common stock. At our option, at any time on or after March 30, 2002, the debentures may be prepaid by conversion of the principal into common stock at the conversion price of \$14.50, cash or any combination thereof and payment of any accrued interest as described above, provided that the average per share market value for the twenty consecutive trading days immediately preceding the date of prepayment equals or exceeds \$38.67 per share. The notes mature on March 29, 2004 and are payable in cash. The warrants grant the right to purchase one share of common stock at the exercise price of \$21.75 for each \$50.00 in face value of the convertible notes at any time before March 30, 2004. Approximately \$2,318,000 of the \$20,000,000 financing is allocated to the estimated fair value of the warrants and is included in additional paid in capital. This amount is amortized as a non-cash charge to interest expense over the life of the debentures using the effective interest rate method.

In May 1999, we filed a registration statement for 2,096,333 shares of common stock, of which 2,046,333 relates to the conversion of the debentures, payment of interest and exercise of the warrants. All shares have been reserved for issuance. The Securities and Exchange Commission declared this registration statement effective on May 27, 1999.

Debt issuance costs are included in other assets and are amortized to interest expense over the life of the debentures using the effective interest rate method.

5. Commitments:

## Lease Obligations

We occupy our current premises under a lease that expires on September 30, 2004. This lease has three options to extend the term for an additional five years per option. We have provided written notice to the landlord of our intent to lease all of the remaining space at this primary facility starting November 1, 1999. Taxes, insurance and operating expenses are our responsibility under the terms of the lease. We also have a second lease for warehouse and office space that expires on October 31, 1999. In January 1999, we entered into a noncancelable operating lease for certain office equipment.

In May 1999, we entered into a lease for approximately 65,000 square feet of additional office and warehouse space in Canton, Massachusetts at an annual average base rent of approximately \$442,598, plus operating expenses. This lease has three options to extend the term for an additional five years per option.

Future minimum lease payments are as follows (in thousands):

1999	\$791
2000	1,240
2001	1,261
2002	1,281
2003	1,267
Thereafter	<u>1,038</u>
	<u>\$6,878</u>

#### Construction-in-Progress

At June 30, 1999, we had approximately \$2,978,000 in construction in progress relating to expansion of our main facility. Additionally, we have committed approximately \$2.1 million for this build-out. The total project cost is estimated at about \$5.9 million.

Interest cost incurred during the period of construction in progress relating to expansion of our main facility is capitalized. The interest cost capitalized for the six months ended June 30, 1999 was \$58,000. No interest was capitalized in 1998.

#### Series C Preferred Stock Commitment

At June 30, 1999, we had approximately 62 shares of Series C convertible preferred stock outstanding. In the event that any Series C preferred stock are outstanding on the mandatory conversion date of March 26, 2000, we have the option of redeeming any such outstanding Series C preferred stock by: (1) paying cash equal to the product of the number of Series C preferred stock outstanding multiplied by the stated value of \$100,000 per share; (2) issuing common stock equal to 1.15 of the stated value divided by the average of the closing bid prices for the 20 consecutive trading days prior to the mandatory conversion date; or (3) any combination of these methods.

#### Purchase of Technology

In April 1999, we purchased certain equipment and intellectual property of Baxter Healthcare Corporation relating to the research and development for the design and manufacturing of key mechanical components of an extracorporeal bioartificial liver device. The purchase price consists of the reissuance of 50,000 shares of common stock held in treasury. In May 1999, we filed a registration statement registering all 50,000 of these shares, 25,000 of which are subject to a one-year lock-up agreement. Additionally, we may be required to make a future cash payment that is contingent on the average closing price of our common stock over the twenty consecutive trading days immediately prior to the earlier of the date we receive FDA approval of an Investigational Device Exemption for a liver assist device or January 1, 2003. We will have no obligation to make such future cash payment if at any time during the period between April 2000 and the date such cash payment is otherwise payable by us, the value of the shares of common stock issued to Baxter is equal to or greater than \$1,000,000. Total consideration is \$1,000,000 of which \$900,000 is a one-time, non-cash charge for the three and six months ended June 30, 1999, with the remainder of this purchase capitalized to property and equipment.



6. Treasury Stock:

In September 1998, the Board of Directors authorized a common stock repurchase program. Repurchases are allowed through open-market transactions for up to 500,000 shares that will provide us with treasury shares for general corporate purposes. During the first half of 1999, we repurchased 70,000 shares of common stock for an aggregate purchase price of approximately \$748,000 and reissued 50,000 shares of common stock related to the purchase of technology (see "Purchase of Technology" note). We had in treasury 40,000 shares of common stock at a cost of \$391,000 and 60,000 shares of common stock at a cost of \$600,000, at December 31, 1998 and June 30, 1999, respectively.

7. Other Revenues:

During the first quarter of 1999, Novartis agreed to provide funding for certain programs to be conducted by Organogenesis. We have recorded other income from Novartis of \$93,000 and \$232,000 for the three and six months ended June 30, 1999 relating to our initiation of these programs. This amount is included in "Product sales to related party, royalties and other income".

8. Research, Development and Operations:

In addition to research and development, this cost category includes expenses of our manufacturing and related operating support departments and costs to manufacture products for research and for sale as we continue our expansion.

	For the Three Months <u>Ended June 30,</u>		For the Six Months <u>Ended June 30,</u>	
	<u>1998</u>	<u>1999</u>	<u>1998</u>	<u>1999</u>
Research and development	\$2,176	\$2,878	\$4,451	\$5,666
Operations and production	<u>1,697</u>	<u>2,690</u>	<u>3,335</u>	<u>4,995</u>
Total research, development and operations	<u>\$3,873</u>	<u>\$5,568</u>	<u>\$7,786</u>	<u>\$10,661</u>

**ORGANOGENESIS INC.**

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-Q contains forward-looking statements that involve risks and uncertainties. Forward-looking statements include information on:

. Our business outlook and future financial performance; . Anticipated profitability, revenues, expenses and capital expenditures; . Future funding and expectations as to any future events; and . Other statements that are not historical fact and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties.

Although we believe that our plans, intentions and expectations reflected in or suggested by such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Form 10-Q and in other publicly available filings with the SEC, such as our Annual Report on Form 10-K for the year ended December 31, 1998. The risk and other factors noted throughout this Form 10-Q could cause our actual results to differ materially from the results contained in any forward-looking statements.

In Management's Discussion and Analysis, we explain the general financial condition and results of operations for Organogenesis Inc. As you read this MD&A, referring to our consolidated financial statements contained in Item 1 of this Form 10-Q may be helpful. Results of operations may vary significantly from quarter to quarter depending on, among other factors, the progress of our research and development efforts, the receipt of milestone and research and development support payments, if any, from Novartis, product revenues, manufacturing costs, the timing of certain expenses and the establishment of additional collaborative agreements, if any.

Overview of Organogenesis Inc.

Organogenesis designs, develops and manufactures medical therapeutics containing living cells and/or natural connective tissue. The company was formed to advance and apply the emerging field of tissue engineering to major medical needs. Our product development focus includes living tissue replacements, cell- based organ assist devices and other tissue-engineered products.

Our Lead Product, Apligraf(R)

On May 22, 1998, our lead product, Apligraf(R) living skin construct, was approved for marketing in the US for the treatment of venous leg ulcers, a type of chronic wound. Apligraf is the only manufactured product containing living human cells to be approved for marketing through the FDA PMA process. Novartis Pharmaceuticals Corporation launched Apligraf in the US in June 1998. Novartis Pharma AG has global Apligraf marketing rights and also markets Apligraf in Canada. Novartis expects to initiate product introduction among key physicians in select European countries in the fall of 1999.

Apligraf(R) is a registered trademark of Novartis.

The next large potential market for Apligraf is expected to be diabetic foot ulcers. The Apligraf pivotal trial in diabetic foot ulcers has been completed and the data are being analyzed. We plan to present these data at a medical meeting in August and to submit a PMA supplement for diabetic foot ulcers to the FDA within the next six months. An eighteen-patient study of Apligraf in the treatment of epidermolysis bullosa, a genetic skin disease, has been completed under an investigator-sponsored investigational device exemption (IDE). The data from this study have been submitted to the FDA. Data have also been presented and/or published with Apligraf in the treatment of burns, wounds due to dermatologic surgery and donor site wounds. A pivotal trial to assess the effect of Apligraf on the cosmetic outcome of wounds due to skin cancer removal is underway.

#### Our Pipeline

Our pipeline includes Vitrix(TM) soft tissue replacement product, a bioartificial liver and a vascular graft, as well as the GraftPatch(TM) and engineered collagen fibril technology out-licensing opportunities. We also market an in-vitro testing product, TestSkin II. We have an active and expanding business development program related to our products and technologies.

#### Results of Operations:

##### Revenues

Total revenues were \$938,000 and \$1,618,000 for the three and six months ended June 30, 1999 compared to \$5,379,000 and \$7,645,000, for the same periods in 1998. Research and development support under the collaborative agreement with Novartis was \$4,750,000 and \$6,750,000 for the three and six months ended June 30, 1998. No research and development support payments were earned in the first half of 1999 under this agreement. Product sales to related party, royalties and other income increased to \$624,000 and \$1,111,000 for the three and six months ended June 30, 1999, compared to \$308,000 and \$502,000, for the same periods in 1998 due to increased sales of product to Novartis and Novartis funding of certain programs. We expect Apligraf commercial sales to increase. Interest income was \$314,000 and \$507,000 for the three and six months ended June 30, 1999, compared to \$321,000 and \$393,000 for the same periods in 1998. The six month increase was primarily due to the difference in funds available for investment.

##### Costs and Expenses

#### Research, development and operations expenses: Our R&D and operations

expenses were \$5,568,000 and \$10,661,000 for the three and six months ended June 30, 1999, compared to \$3,873,000 and \$7,786,000 for the same periods in 1998. The increase is primarily due to personnel additions in the research, development and clinical groups, as well as personnel additions in manufacturing and quality systems. Activities for this period that account for the increased costs also include expansion of Apligraf operations, the Apligraf diabetic ulcer and cosmetic outcome pivotal trials, the VITRIX(TM) soft tissue replacement preclinical program, and the liver assist device research program. Production costs exceeded product sales due to the start-up costs of new product introduction and the high costs associated with low volume production. We expect production volume to increase and our margins to improve. We expect to continue to expand manufacturing operations and advance the product pipeline during 1999.

General and administrative expenses: Our G&A expenses increased to

\$1,654,000 and \$3,168,000 for the three and six months ended June 30, 1999, compared to \$1,191,000 and \$2,411,000 for the same period in 1998. The increase was primarily due to personnel additions and increased professional fees.

Other costs and expenses: Included in costs and expenses is a one-time,

non-cash charge of \$900,000 relating to the purchase of technology. Interest expense was \$405,000 for the three and six months ended June 30, 1999 due to the issuance of convertible debentures in March 1999.

As a result of the net effect described, we incurred a net loss of \$7,589,000, or \$.25 per share (basic and diluted), and \$13,516,000, or \$.44 per share (basic and diluted), for the three and six months ended June 30, 1999, respectively, compared to net income of \$315,000, or \$.01 per share (basic and diluted), and a net loss of \$2,552,000, or \$.09 per share (basic and diluted), for the comparable 1998 periods. We may incur additional losses as expenditures continue to increase due to continued expansion of operations and research programs.

Capital Resources and Liquidity:

## Funds Used in Operations

At June 30, 1999, we had cash, cash equivalents and investments in the aggregate amount of \$20,401,000 and working capital of \$19,112,000, compared to \$17,841,000 and \$15,541,000, respectively, at December 31, 1998. Cash equivalents consist of money market funds, which are highly liquid and have original maturities of less than three months. Investments consist of securities that have an A or A1 rating or better with a maximum maturity of two years. Cash used in operating activities during the six months ended June 30, 1999 was \$12,645,000, compared to \$2,093,000 for the six months ended June 30, 1998, primarily for financing our ongoing research, development and manufacturing operations.

## Capital Spending

Capital expenditures were \$3,690,000 and \$456,000 during the six months ended June 30, 1999 and 1998, respectively, primarily related to further build-out of the current facilities to support Apligraf manufacturing and the acquisition of laboratory equipment for expanded research and development programs. We have committed approximately \$2.1 million to expand our current facility in the areas of Apligraf manufacturing, quality systems labs, and packaging. We also plan to add a second facility in the future to enable further expansion.

## Financing

From inception, we have financed our operations substantially through private and public placements of equity securities, as well as receipt of research support and contract revenues, interest income from investments, sale of products and receipt of royalties. During the six months ended June 30, 1999, financing activities provided additional cash and working capital of \$18,895,000 primarily from the sale of five-year convertible debentures and warrants to purchase common stock that generated gross proceeds of \$20,000,000 and the exercise of stock options of \$218,000. Financing activities provided cash of approximately \$26,032,000 for the six months ended June 30, 1998 from: the sale of 200 shares of Series C convertible preferred stock that generated net proceeds of approximately \$19,117,000; an equity investment of \$6,000,000 from Novartis; and the exercise of stock options of \$915,000.

At June 30, 1999, we had approximately 62 shares of Series C convertible preferred stock outstanding. In the event that any Series C preferred stock are outstanding on the mandatory conversion date of March 26, 2000, we have the option of redeeming any such outstanding Series C preferred stock by: (1) paying cash equal to the product of the number of Series C preferred stock outstanding multiplied by the stated value of \$100,000 per share; (2) issuing common stock equal to 1.15 of the stated value divided by the average of the closing bid prices for the 20 consecutive trading days prior to the mandatory conversion date; or (3) any combination of these methods.

## Liquidity and Other Risk Factors

Based upon our current plans, we believe that the convertible debt financing completed on March 31, 1999, together with existing working capital and future funds from Novartis, including product and royalty revenue, will be sufficient to finance operations into 2000. We will need additional capital within the next year to continue under our current plan. However, this statement is forward-looking and changes may occur that would significantly decrease available cash before such time. Factors that may change our cash requirements include:

- . Delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- . Delays in commercial acceptance and reimbursement when product launches occur;
- . Changes in the progress of research and development programs;
- . Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies; and
- . Acquisition of a second manufacturing plant.

Any of these events could adversely impact our capital resources, requiring us to raise additional funds. Additional funds may not be available when required on acceptable terms. If adequate funds are not available when needed, we would need to delay, scale back or eliminate certain research and development programs or license to third parties certain products or technologies that we would otherwise undertake ourselves, resulting in a potential material adverse effect on our financial condition and results of operations.

Year 2000

The Year 2000 issue ("Y2K") refers to potential problems with computer systems or any equipment with computer chips or software that use dates where the year has been stored as just two digits (e. g., 98 for 1998). On January 1, 2000, any clock or date recording mechanism incorporating date sensitive software which uses two digits to represent the year may recognize a date using 00 as the year 1900 rather than the year 2000. This could result in a system failure or miscalculations causing disruption of operations, including, among other things, a temporary inability to manufacture product or process transactions, send invoices or engage in similar business activities.

## State of Readiness

In order to address this situation, we conducted an assessment to identify and determine the Y2K readiness of our systems. This assessment program focused on three main functional areas, including:

- . Information technology which addresses data, phone and administrative systems; . Embedded chip technology which addresses manufacturing systems, laboratory instruments and plant maintenance systems with programmable logic controllers with date functions; and . Material suppliers, vendors and other third parties that address areas that are critical to the manufacturing process, distribution of product or other business processes.

The task of assessment from a Y2K readiness perspective is 100% complete. Some of our systems are Y2K compliant, whereas other systems have been identified as not being Y2K compliant and remedial action is underway and nearly complete. In addition to the assessment of systems, key vendors, suppliers and other third parties were identified and a survey form was sent to each of these business entities to determine if their systems are Y2K compliant. We are monitoring responses as they are received. Y2K issues with our vendors, suppliers or other third parties could delay the shipment and receipt of critical supplies, potentially impacting production and operations. We are proactively addressing the Y2K issue with vendors, suppliers and other third parties to minimize risk from these external factors.

## Cost of Year 2000 Compliance and Contingency Plans

While our Y2K project is not yet complete, we currently estimate that costs associated with the Y2K issue will be no more than \$250,000, which includes the use of internal resources. Working capital will be used to fund these costs. To date, costs consist primarily of payroll costs for existing employees, including the information technology group, which are not separately tracked, as well as certain hardware and software upgrades and training costs. However, certain aspects of the Y2K assessment are still ongoing. If we or key third parties such as suppliers and customers are not Y2K ready, there could be an adverse effect on our business, results of operations and financial condition. We believe that with the implementation of the Y2K program the risk of significant interruptions of normal operations is reduced. We are developing a contingency plan to address a situation in which Y2K problems do cause an interruption in normal business activities. Contingency plans and related cost estimates will be continually refined as additional information becomes available.

Additional Cautionary Considerations:

We are subject to risks common to entities in the biotechnology industry, including, but not limited to, the following uncertainties:

. Market acceptance of our products, if and when approved, and successful marketing and selling of Apligraf by Novartis; . FDA approval of Apligraf for other indications and successful registrations of Apligraf outside the US; . Risk of failure of clinical trials for future indications of Apligraf and other products; . Compliance with FDA regulations and similar foreign regulatory bodies; . Risk of manufacturing disruptions or production failures; . Manufacture and sale of products in sufficient volume to realize a satisfactory margin; . Continued availability of raw material for products; . Availability of sufficient product liability insurance; . Ability to recover the investment in property and equipment; . Protection of proprietary technology through patents; . Development by competitors of new technologies or products that are more effective than ours; . Adequate third-party reimbursement for products; . Dependence on and retention of key personnel; . Year 2000 issues; and . Availability of additional capital on acceptable terms, if at all.

**ORGANOGENESIS INC.****PART II - OTHER INFORMATION**

## Item 4. Submission of Matters to a Vote of Security Holders

We held our Annual Meeting for Stockholders on May 14, 1999. At the meeting, Messrs. Richard S. Cresse, Albert Erani, Bjorn R. Olsen, Ms. Marguerite A. Piret, David T. Rovee, Anton E. Schrafl and Herbert M. Stein, were re-elected as Directors. The vote with respect to each nominee is set forth below:

	<u>Vote For</u>	<u>Vote Withheld</u>
Mr. Cresse	27,875,700	493,627
Mr. Erani	27,872,991	496,336
Dr. Olsen	27,872,607	496,720
Ms. Piret	27,875,943	493,384
Dr. Rovee	27,872,569	496,758
Dr. Schrafl	27,875,943	493,384
Mr. Stein	27,875,700	493,627

In addition, the stockholders authorized the following:

- . An increase in the number of authorized shares of common stock from 40,000,000 to 80,000,000 shares, by a vote of 27,669,495 shares for, 622,265 shares against, 77,567 shares abstaining and 2,084,973 shares non-voting;
- . An amendment to our 1991 Employee Stock Purchase Plan to extend the plan for an additional five years and to adjust the number of shares authorized to be issued under each offering period to 30,000; by a vote of 12,780,923 shares for, 882,339 shares against, and 143,578 shares abstaining;
- . An amendment to our 1995 Stock Option Plan to increase the number of shares of common stock available for issuance pursuant to options granted from 2,929,688 to 5,000,000; by a vote of 12,034,104 shares for, 1,608,147 shares against, and 164,588 shares abstaining;
- . The ratification of the selection by the Board of Directors of PricewaterhouseCoopers LLP as our independent accountants for the 1999 fiscal year; by a vote of 28,220,644 shares for, 88,533 shares against, 60,150 shares abstaining and 2,084,973 shares non-voting.



Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

3(i) Restated Certificate of Incorporation of the Company as amended

10(m) Lease Agreement between North Queen Street LP and the Company, dated as of May 21, 1999

10(n) First Amendment to Lease Agreement between North Queen Street LP and the Company, dated as of June 18, 1999

10(o) Asset Purchase Agreement between the Company and Baxter Healthcare Corporation, dated as of April 14, 1999

27 Financial Data Schedule (filed with electronic submission only)

(b) No current reports on Form 8-K were filed during the quarter ended June 30, 1999.

**ORGANOGENESIS INC.**

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Organogenesis Inc.  
(Registrant)

Date: August 16, 1999

/s/ Herbert M. Stein

Herbert M. Stein, Chairman  
and Chief Executive Officer  
(Principal Executive Officer)

Date: August 16, 1999

/s/ Donna Abelli Lopolito

Donna Abelli Lopolito, Vice President Finance and  
Administration, Chief Financial Officer,  
Treasurer and Secretary  
(Principal Financial and Accounting Officer)